

Food and Drug Administration
Washington DC 20204

Arthur A. Siciliano, Ph.D.
Executive Vice President
Polymedica Industries, Inc.
11 State Street
Woburn, Massachusetts 01801

AUG 29

Re: Nutritional Support Statement Notification

Dear Mr. Siciliano:

This acknowledges receipt on July 25, 1995, of your letter, dated July 24, 1995, notifying the Food and Drug Administration (FDA) that the dietary supplement product, Azo-Cranberry™ Cranberry Juice Powder Capsules, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,

Margaret C. Binzer
Consumer Safety Officer
Regulatory Branch
Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0162

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